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Annex to the Accreditation Certificate D-EP-19851-01-00 according to DIN EN ISO/IEC 17043:2010

Valid from: **05.06.2023**

Date of issue: 05.06.2023

Holder of accreditation certificate:

ESfEQA GmbH
Siemensstraße 38, 69123 Heidelberg, Germany

The proficiency testing provider meets the requirements of DIN EN ISO/IEC 17043:2010 to carry out the conformity assessment activities listed in this annex. The proficiency testing provider meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO/IEC 17043 are written in the language relevant to the operations of proficiency testing providers and confirm generally with the principles of DIN EN ISO 9001.

Medical Laboratory Diagnostics

Investigation Fields:
Clinical Chemistry, Microbiology, Virology

Using the proficiency testing materials:
Whole blood, serum, plasma, urine, hemolysate, lyophilized bacteria strains and aqueous solution.

The Proficiency Testing Provider maintains a current list of all proficiency tests in the field of accreditation.

This certificate annex is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at https://www.dakks.de.

Abbreviations used: see last page

Investigation Field: Clinical Chemistry

Testing field	Matrix/Products	Test parameters/ Analytes[1]	Proficiency Testing Programs[1]
Biochemistry	Serum, Plasma	Albumin, Alkaline Phosphatase, ALT/GPT, Amylase, Amylase pancreatic, AST/GOT, Bilirubin direct, Bilirubin total, Calcium, Calcium (ionized), Chloride, Cholesterol, Cholinesterase, Creatinkinase, Copper, Creatinine, Gamma-GT, Glucose, HDL-Cholesterol, Iron, Lactate, Lactate-Dehydrogenase, LDL-Cholesterol, Lipase, Lithium, Magnesium, Phosphate, Potassium, Sodium, TIBC Total Iron Binding Capacity, Total Protein, Triglycerides, Urea, Uric Acid, Zinc	Clinical Chemistry (CC4, CC12)
Urin Chemistry	Urine	Albumin, Amylase, Calcium, Chloride, Creatinine, Glucose, Magnesium, Phosphate, Potassium, Total Protein, Sodium, Urea, Uric Acid	Urine Chemistry (UC)
Cardiac Marker	Serum, Plasma	BNP, CK-MB (mass), CK-MB (activity), Homocysteine, Myoglobin, NT-proBNP, Troponin I, Troponin T	Cardiac Marker (CM4, CM12)
Glycated Hemoglobin	Whole blood, hemolysate	HbA1c, Hemoglobin	Glycated Hemoglobin (GHB)
Ethanol, Ammonia and Bicarbonate	Aqueous solution	Ethanol, Ammonia, Bicarbonate	Ethanol, Ammonia and Bicarbonate (ETH)

Testing field	Matrix/Products	Test parameters/ Analytes[1]	Proficiency Testing Programs[1]
Therapeutic Drug Monitoring	Serum, Plasma	Amikacin, Carbamazepine, Chinidine, Chloramphenicol, Digoxin, Disopyramid, Ethosuximid, Gentamicin, Lidocain, NAPA, Paracetamol, Phenobarbital, Phenytoin, Primidon, Procainamide, Salicylate, Theophylline, Tobramycin, Valproic acid, Vancomycin	Therapeutic Drugs (TDM)
Drugs of Abuse	Urine	Acetylmorphine, Amphetamines, Benzo-diazepines, Buprenor-phine, Cannabinoids, Cocaine, Barbiturates, Methadone, Opiates, Synthetic Cannabinoids (K2/Spice), Tricyclic Antidepressants	Drogen (DAT)
Urine Rapid Testing	Urine	Bilirubin, Glucose, HCG, Hemoglobin, Ketone, Leucocytes, Nitrite, pH, Specific Gravity, Total Protein, Urobilinogen	Qualitative Urine Analysis (US)
Urine Sediment	Urine	Bacteria, Casts, Crystals, RBC, WBC qualitative, semi-quantitative and quantitative	Urine Sediment (USEDL cytometric, USEDM microscopic)
Blood Gas	Aqueous solution	Calcium, Chloride, Glu-cose, Lactate, pCO_2, pH, pO_2, Potassium, Sodium, Urea	Blood Gas and Electrolytes (BG)
Fecal Occult Blood	Aqueous Solution	Human Hemoglobin in faeces	Fecal Occult Blood (FOB)

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Testing field	Matrix/Products	Test parameters/ Analytes[1]	Proficiency Testing Programs[1]
Coagulation	Plasma	aPTT, Antithrombin III, D-Dimer, Fibrinogen, Prothrombin time, Protein C, Protein S	Coagulation (COA4, COA12)
Tumor Marker	Serum, Plasma	AFP, CEA, CA 19-9, CA 125, CA 15-3, CA 72-4, Cyfra 21-1, Ferritin, PSA total, PSA free, PSA complex	Tumor Marker (TM4, TM12, TMH4, TMH12)
Hormones	Serum, Plasma	Aldosterone, AMH, Androstendione, Calcitonin, C-Peptid, Cortisol, DHEA-S, Estriol, Folate, FSH, hCG, Homocystein, human growth hormone, IgE, Insulin, LH, Methylmalonic acid, Estradiol, Pro-gesterone, Prolactin, PTH, SHBG, Testosterone, Thyreoglobulin, T3 free, T3 total, T4 free, T4 total, TSH, Vitamin B12, Vitamin D, 17-OH-Progesterone	Hormones (HOR4, HOR12, TMH4, TMH12, HCG)
hCG	Serum, Plasma	qualitative: hCG	HCG
Specific Proteins	Serum, Plasma	Albumin, Alpha-1-acid Glycoprotein, Alpha-1-Antitrypsin, Alpha-2-Macroglobulin, ASO, Beta-2-Microglobulin, C3, C4, Ceruloplasmin, CRP, Haptoglobin, IgA, IgE, IgG, IgM, Kappa light chains free, Lambda light chains free, Prealbumin, RF, Transferrin	Specific Proteins (SP4, SP12)
Thyroid antibodies	Serum, Plasma	Thyroglobulin-antibody (anti-TG), Thyroperoxidase antibody (anti-TPO), TSH receptor antibody (TRAk)	Thyroid antibodies (ANTI-THYR)
Procalcitonin	Serum	Procalcitonin	PCT

Testing field	Matrix/Products	Test parameters/ Analytes[1]	Proficiency Testing Programs[1]
Hemogram	Whole Blood	HGB, HCT, MCH, MCHC, MCV, PLT, RBC, WBC, RDW, MPV	Hemogram (HEM4, HEM12)
Hemogram	Whole Blood	HGB, HCT, MCH, MCHC, MCV, PLT, RBC, WBC, RDW, MPV, LYMPH %, LYMPH, MID %, MID, MONO %, MONO, MXD %, MXD, NEUT %, NEUT	Hemogram incl. 3-part Diff. (HEM3D)
Erythrocyte Sedimentation Rate	Whole Blood	ESR	ESR

[1] exemplary list

Investigation Field: Microbiology

Testing field	Matrix/Products	Test parameters/ Analytes[1]	Proficiency Testing Programs[1]
Serology	Plasma	qualitative: Antibodies against Treponema pallidum, Non-Treponemal (lipoid) Antibodies	Syphilis (SYP)
Serology	Plasma	qualitative: Antibodies against Trypanosoma cruzi	Chagas (CHA)
Serology	Plasma	qualitative: Antibodies (IgG, IgM, IgA) against Chlamydophila pneumoniae	Chlamydia pneumoniae (CHP)
Serology	Plasma	qualitative: Antibodies (IgG, IgM, IgA) against Chlamydia trachomatis	Chlamydia trachomatis (CHT)
Serology	Plasma	qualitative: Antibodies (IgG, IgM) against Borrelia	Borrelia (BOR)
Bacteriology	Lyophilized bacteria strains	Identification (genus and species), Antibiotic susceptibility testing	Bacteriology (BAC)
Serology	Plasma	qualitative: Antibodies (IgG, IgM, IgA) against Brucella, Agglutinating Antibodies against Brucella	Brucella (BRU)

Testing field	Matrix/Products	Test parameters/ Analytes[1]	Proficiency Testing Programs[1]
Serology	Plasma	qualitative: Antibodies (IgG, IgM) against Leptospira	Leptospira (LEP)

[1] exemplary list

Investigation field: Virology

Testing field	Matrix/Products	Test parameters/ Analytes[1]	Proficiency Testing Programs[1]
Serology	Plasma	qualitative: anti-HAV IgG + total, anti-HAV IgM	Hepatitis A Virus (HAV)
Serology	Plasma	qualitative: anti-HBs, anti-HBc, anti-HBe, HBeAg, anti HBc IgM qualitative and quantitative: HBsAg	Hepatitis B Virus (HBV)
Serology	Plasma	qualitative: anti-HIV 1/2, anti-HCV, anti-HBc, HBsAg	Infectious Disease Combination Control (INF)
Serology	Plasma	qualitative: anti-VZV IgG + total, anti-VZV IgM, anti VZV IgA	Varicella Zoster Virus (VZV)
Serology	Plasma	qualitative: anti-EBV VCA IgG + total, anti-EBV EBNA-1 IgG + total, anti-EBV VCA IgM	Epstein-Barr Virus (EBV)
Serology	Plasma	qualitative: anti-Rubella IgG + total, anti-Rubella IgM, anti-CMV IgG + total, anti-CMV IgM, anti-HSV 1/2 IgG + total, anti-HSV 1/2 IgM	ToRCH (TORCH)
Serology	Plasma	qualitative: antibodies (IgG, IgM) against Parvovirus B19	Parvovirus B19 (PAR)
Serology	Plasma	qualitative: antibodies (IgG, IgM) against Measles virus	Masern (MEA)
Serology	Plasma	qualitative: anti HTLV I/II	HTLV I/II (HTL)
Serology	Plasma	qualitative: anti-HEV (IgG, IgM)	Hepatitis E Virus (HEV)

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Testing field	Matrix/Products	Test parameters/ Analytes[1]	Proficiency Testing Programs[1]
Serology	Plasma	qualitative: anti-Chikungunyavirus (IgG, IgM)	Chikungunyavirus (CHIKV); Mosquito-transmitted Diseases (MTD)
Serology	Plasma	qualitative: anti-Denguevirus (IgG, IgM)	Denguevirus (DENV); Mosquito-transmitted Diseases (MTD)
Serology	Plasma	qualitative: anti-West-Nile-Virus (IgG, IgM)	West-Nile-Virus (WNV); Mosquito-transmitted Diseases (MTD)
Serology	Plasma	qualitative: anti-Zika Virus (IgG, IgM)	Zika Virus (ZIKV); Mosquito-transmitted Diseases (MTD)
Serology	Plasma	Qualitative:IgA, IgG, IgM and total Antibodies against SARS-CoV-2	SARS-CoV-2 Antibodies (COVID)
Antigen detection	Aqueous solution (lyophilised)	qualitative: SARS-CoV-2 Antigen	SARS-CoV-2 Antigen (COVAG)
Molecular biology	Aqueous solution (lyophilised)	qualitative: SARS-CoV-2 RNA	SARS-CoV-2 Molecular (COVM)

[1] exemplary list

Investigation Field: Transfusion medicine

Testing field	Matrix/Products	Test parameters/ Analytes	Proficiency Testing Programs[1]
Immunohaematology	Erythrocyte suspension, Serum, Whole Blood	ABO-system, A subgroups, Rh-Factor D, Rh-formula, Kell antigen, Direct Coombs Test, Irregular antibodies (antibody screening/Indirect Coombs Test), Antibody identification, Compatibility testing (crossmatch)	Immunohaematology (IMHEM)
Blood grouping	Erythrocyte suspension, Serum, Whole Blood	ABO-system, Rh-Factor D	Blood grouping (ABO)

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Abbreviations used:

DIN	Deutsches Institut für Normung e.V. – German institute for standardization
EN	Europäische Norm – European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardisation